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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,993	03/23/2004	James Patrick Dunn	R0169B-REG	4667

24372 7590 10/03/2006

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EXAMINER
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RAO, DEEPAK R

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/807,993	DUNN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Deepak Rao	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-40 are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-36 and 39 are allowed.
- 6) ☒ Claim(s) 37-38, 40 are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                              | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>  \  </u> | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This office action is in response to the amendment filed on August 30, 2006.

Claims 1-40 are pending in this application.

#### ***Withdrawn Rejections/Objections:***

Applicant is notified that any outstanding rejection/objection that is not expressly maintained in this office action has been withdrawn or rendered moot in view of applicant's amendments and/or remarks.

#### ***The following rejections are under new grounds:***

##### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 40 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pharmaceutical composition for treating a disease mediated by HIV-1 in a host, does not reasonably provide enablement for a composition for treating diseases mediated by human immunodeficiency or inhibit HIV generally. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The reasons provided in the previous office action are incorporated here by reference (relevant portion from previous office action provided below for convenience):

Art Unit: 1624

The instant claims appear to be in 'reach-through' format. Reach through claims, in general have a format drawn to mechanistic, receptor binding or enzymatic functionality and thereby reach through any or all diseases, disorders or conditions, for which they lack written description and enabling disclosure in the specification. Further, there is no disclosure regarding how the host in need of such activity is identified and how the host is subjected to the treatment HIV infection generally. See MPEP § 2164.03 for enablement requirements in cases directed to structure-specific arts such as the pharmaceutical art.

The scope of the method claims is not adequately enabled solely based on the test assays to measure the inhibition activity in a HIV-1 RT assay provided in the specification in Example 45 at pages 150-151. First, the instant claims cover 'a method of treating or preventing an HIV infection or treating AIDS or ARC' generally, which for example, includes conditions caused by HIV-1, HIV-2, etc. that are known to exist and those that may be discovered in the future, for which there is no enablement provided. The use disclosed in the specification is as Non-nucleoside reverse transcriptase inhibitors, useful to treat all types of HIV infections, which include AIDS, etc. Test procedure and assay relied upon at pages 150-151 is drawn to inhibition of HIV-1 reverse transcriptase and results for some of the exemplified compounds are provided in Table 3. There is nothing in the disclosure regarding how this *in vitro* data correlates to the treatment of **all** types of HIV infections or conditions associated with HIV embraced by the instant claims. One of ordinary skill would not know to extrapolate this test data to compounds having the assorted types of substituents provided in the instant claims. The disorders encompassed by the instant claims include AIDS, etc., some of which have been proven to be extremely difficult to treat. There is no reasonable basis for assuming that the myriad of compounds embraced by the claims will all share the same physiological properties since they are so structurally dissimilar as to be chemically non-equivalent and there is no basis in the prior art for assuming the same. Note *In re Surrey*, 151 USPQ 724 regarding sufficiency of disclosure for a Markush group.

**Note:** The instant composition claim 40 recites a particular 'intended use' in the claim.

See MPEP § 2164.01(c). When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated based on that limitation. In contrast, when a compound or composition claim is not limited by a recited use, any enabled use that would reasonably correlate with the entire scope of that claim is sufficient to preclude a rejection for nonenablement based on how to use.

Art Unit: 1624

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37-38 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

1. Claim 37 is improperly dependent on claim 32. Claim 37 recites “A method for inhibiting HIV-1 reverse transcriptase comprising administering a compound according to claim 32”, however, claim 32 is drawn to “A method for treating an HIV-1 infection” and not ‘a compound’. Therefore, the recitation “a compound according claim 32” in claim 37 is confusing.
2. Claim 38 recites the limitation “A method according to claim 37 wherein the host is infected...” in line 1, for which there is insufficient antecedent basis in claim 37 on which claim 38 is dependent. Claim 37 does not recite the term “host”.
3. In claim 40, the recitation in the last two lines – “for treating diseases mediated by human immunodeficiency virus inhibit HIV” is not clear.

***Allowable Subject Matter***

Claims 1-36 and 39 are allowed. The references of record do not teach or fairly suggest the instantly claimed compounds.

Art Unit: 1624


***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**Deepak Rao**  
**Primary Examiner**  
**Art Unit 1624**

September 28, 2006